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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,642	04/08/2004	Eric G. Lovett	GUID.611PA	8502

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EXAMINER	
MULLEN, KRISTEN DROESCH	
ART UNIT	**PAPER NUMBER**
3766	

MAIL DATE	DELIVERY MODE
09/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/820,642	LOVETT ET AL	
	Examiner	Art Unit	
	Kristen Droesch Mullen	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *9-12,45,46,58 and 59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,13-44,47-57 and 60-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/23/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/16/07 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-5, 8, 13-14, 19-25, 28-29, 33-41, 44, 47-54, 57 and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy et al. (2002/0035376) in view of Heinrich (2002/0082658).

Regarding claim 1, Bardy shows a system comprising detection circuitry, energy delivery circuitry; therapy instructions stored in the energy delivery circuitry, the therapy instructions executable to direct delivery of the plurality of cardiac therapies; one or more electrodes configured for subcutaneous non-intrathoracic placement and for coupling to the detection circuitry and energy delivery circuitry, detection circuitry configured to receive cardiac signals using the one or more electrodes and detect a tachycardia condition a bradycardia condition, using the cardiac signals; and a controller coupled to the detection circuitry and energy delivery circuitry, the controller, in response to a cardiac condition requiring treatment, executing at least some of the therapy instructions to coordinate delivery of a selected *one of* the tachycardia, bradycardia, and asystole prevention therapies (Paragraphs [0039], [0040], [0043]; Figs. 4-6, 9, 11, 15). Although Bardy fails to specifically teach detecting an asystole condition and the asystole prevention therapy is delivered upon detection of the asystole condition, attention is directed to Heinrich who teaches detecting an asystole condition and the asystole prevention therapy is delivered upon detection of the asystole condition (paras. [0064, 0066, 0067]). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Bardy to further include detecting an asystole condition and delivery of the asystole prevention therapy upon detection of the asystole condition as taught by Heinrich in order to provide a multifunctional implantable anti-arrhythmia device that provides therapy for all possible arrhythmias (bradycardia, tachycardia, asystole, etc.) that may be encountered in a patient.

With respect to claim 21, Bardy shows a system including a housing configured for subcutaneous, non-intrathoracic placement; detection circuitry provided in the housing, energy

delivery circuitry provided in the housing, one or more electrodes configured for subcutaneous, non-intrathoracic placement and coupled to the detection circuitry and energy delivery circuitry, and a controller provided in the housing and coupled to the detection circuitry and energy delivery circuitry, the controller, in response to a cardiac condition requiring treatment, delivering a selected *one of* the tachycardia, bradycardia, and asystole prevention therapies (Paragraphs [0039], [0040], [0043]; Figs. 4-6, 9, 11, 15).). Although Bardy fails to specifically teach detecting an asystole condition and the asystole prevention therapy is delivered upon detection of the asystole condition, attention is directed to Heinrich who teaches detecting an asystole condition and the asystole prevention therapy is delivered upon detection of the asystole condition (paras. [0064, 0066, 0067]). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Bardy to further include detecting an asystole condition and delivery of the asystole prevention therapy upon detection of the asystole condition as taught by Heinrich in order to provide a multifunctional implantable anti-arrhythmia device that provides therapy for all possible arrhythmias (bradycardia, tachycardia, asystole, etc.) that may be encountered in a patient.

Regarding claim 37, Bardy shows a method including sensing cardiac activity from a subcutaneous, non-intrathoracic location detecting a cardiac condition necessitating treatment in response to the sensed cardiac activity, and delivering *one of* a plurality of cardiac therapies to treat the detected cardiac condition, the plurality of cardiac therapies comprising at least a tachycardia therapy, a bradycardia therapy, and an asystole prevention therapy (Paragraphs [0039], [0040], [0043]; Figs. 4-6, 9, 11, 15).). Although Bardy fails to specifically teach detecting an asystole condition and the asystole prevention therapy is delivered upon detection of

the asystole condition, attention is directed to Heinrich who teaches detecting an asystole condition and the asystole prevention therapy is delivered upon detection of the asystole condition (paras. [0064, 0066, 0067]). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Bardy to further include detecting an asystole condition and delivery of the asystole prevention therapy upon detection of the asystole condition as taught by Heinrich in order to provide a multifunctional implantable anti-arrhythmia device that provides therapy for all possible arrhythmias (bradycardia, tachycardia, asystole, etc.) that may be encountered in a patient.

The examiner has treated the "means for" limitations of claim 50 as invoking 35 U.S.C. 112, 6th paragraph. One with ordinary skill in the art will understand that the structure of the sensing circuitry (204) and subcutaneous electrodes (214) will perform the recited function of "sensing cardiac activity from a subcutaneous non-intrathroacic location", and the diagnostics circuitry (210) will perform the recited function of "detecting a cardiac condition in response to the sensed cardiac activity" and the shock therapy circuitry (216) and pacing therapy circuitry (230) will perform the function of "delivering one of a plurality of cardiac therapies". Although Bardy fails to specifically teach detecting an asystole condition and the asystole prevention therapy is delivered upon detection of the asystole condition, attention is directed to Heinrich who teaches detecting an asystole condition and the asystole prevention therapy is delivered upon detection of the asystole condition (paras. [0064, 0066, 0067]). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Bardy to further include detecting an asystole condition and delivery of the asystole prevention therapy upon detection of the asystole condition as taught by Heinrich in order to provide a

multifunctional implantable anti-arrhythmia device that provides therapy for all possible arrhythmias (bradycardia, tachycardia, asystole, etc.) that may be encountered in a patient.

The examiner considers that Bardy shows equivalent structure to the means for sensing cardiac activity from a subcutaneous, non-intrathoracic location, the means for detecting a cardiac condition necessitating treatment in response to the sensed cardiac activity, and the means for delivering *one of* a plurality of cardiac therapies to treat the detected cardiac condition, the plurality of cardiac therapies comprising at least a tachycardia therapy, a bradycardia therapy, and an asystole prevention therapy (Paragraphs [0039], [0040], [0043]; Figs. 4-6, 9, 11, 15).

Regarding claims 2-5, 22-25, 38-41 and 51-54, Bardy shows the plurality of cardiac therapies comprises a bradycardia pacing, cardiac resynchronization (cardioversion/defibrillation) antitachycardia pacing, and defibrillation (Paragraphs [0039], [0040]).

With respect to claims 8 and 28, Bardy shows the one or more electrodes are configured for cardiac pacing (15, 27, 27', 1417, 1219) and sensing (23, 25, 26, 28, 1425, 1427) (Figs. 1-3, 10, 12-14, 18).

Regarding claim 13, Bardy shows a housing where the circuitry is situated and the housing is configured for implantation (Figs. 1-3, 10, 12-14, 18).

With respect to claims 14 and 29, Bardy shows the one or more electrodes include at least one electrode (15, 26, 28, 1417, 1219, 1425, 1427) disposed on the housing (Figs. 1-3, 10, 12-14, 18).

Regarding claims 19 and 33, Bardy shows a housing within which the detection circuitry, energy delivery circuitry, and controller are situated, the housing is configured for implantation

in a patient and the one or more electrodes (15, 26, 28, 1417, 1219, 1425, 1427) are disposed in or on the housing (Figs. 1-3, 10, 12-14, 18).

With respect to claims 20 and 34, Bardy shows the housing is configured to have an arcuate shape (Figs. 12-14, 18).

Regarding claims 35-36, Bardy shows the one or more electrodes (23, 25, 26, 27, 27', 28) comprise at least one subcutaneous, non-intrathoracic electrode array coupled to the housing via a lead (21) (Figs 1-6, 9-13)

With respect to claims 44, 48, 57 and 60, Bardy shows detecting the cardiac condition at a subcutaneous, non-intrathoracic location (via electrodes 23, 25, 26, 28, 1425, 1427) and energy for the plurality of cardiac therapies is provided from a subcutaneous, non-intrathoracic source (within the housing) (Figs. 1-3, 10, 12-14, 18).

Regarding claims 48-49 and 61-62, Bardy shows delivering monophasic waveforms and delivering multiphasic waveforms (Paragraphs [0039], [0063], [0071]).

The examiner has treated the "means for" limitations of claims 57 and 60-62 as invoking 35 U.S.C. 112, 6th paragraph. One with ordinary skill in the art will understand that the structure of the sensing circuitry (204) and subcutaneous electrodes (214) and diagnostics circuitry (210) will perform the recited function of "detecting the cardiac condition at a subcutaneous non-intrathoracic location", the structure of the power source (220) will perform the recited function of "supplying energy . . . from a subcutaneous non-intrathoracic source" and the shock therapy circuitry (216) and pacing therapy circuitry (230) will perform the function of "delivering monophasic waveforms" and "delivering multiphasic waveforms"

As explained above, the examiner considers that Bardy shows equivalent structure to the means for detecting the cardiac condition at a subcutaneous non-intrathroacic location, the means for supplying energy . . . from a subcutaneous non-intrathroacic source, the means for delivering monophasic waveforms and the means for delivering multiphasic waveforms. See rejections above for claims 57 and 60-62.

The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

4. Claims 1-5, 8, 13-25, 28-41, 44, 47-54, 57 and 60-62 are rejected under 35 U.S.C. 102(a) as being anticipated by Bardy et al. (2002/0091414) in view of Heinrich (2002/0082658).

Regarding claim 1, Bardy shows a system comprising detection circuitry, energy delivery circuitry; one or more electrodes configured for subcutaneous non-intrathoracic placement and for coupling to the detection circuitry and energy delivery circuitry, and a controller coupled to the detection circuitry and energy delivery circuitry, the controller, in response to a cardiac condition requiring treatment, coordinating delivery of a selected *one of* the tachycardia, bradycardia, and asystole prevention therapies (Paragraphs [0035], [0036], [0039]; Figs. 4-6, 9, 11, 15). Although Bardy fails to specifically teach detecting an asystole condition and the asystole prevention therapy is delivered upon detection of the asystole condition, attention is directed to Heinrich who teaches detecting an asystole condition and the asystole prevention therapy is delivered upon detection of the asystole condition (paras. [0064, 0066, 0067]). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Bardy to further include detecting an asystole condition and delivery of the asystole prevention therapy upon detection of the asystole condition as taught by Heinrich in

order to provide a multifunctional implantable anti-arrhythmia device that provides therapy for all possible arrhythmias (bradycardia, tachycardia, asystole, etc.) that may be encountered in a patient.

With respect to claim 21, Bardy shows a system including a housing configured for subcutaneous, non-intrathoracic placement; detection circuitry provided in the housing, energy delivery circuitry provided in the housing, one or more electrodes configured for subcutaneous, non-intrathoracic placement and coupled to the detection circuitry and energy delivery circuitry, and a controller provided in the housing and coupled to the detection circuitry and energy delivery circuitry, the controller, in response to a cardiac condition requiring treatment, delivering a selected *one of* the tachycardia, bradycardia, and asystole prevention therapies (Paragraphs [0035], [0036], [0039]; Figs. 4-6, 9, 11, 15). Although Bardy fails to specifically teach detecting an asystole condition and the asystole prevention therapy is delivered upon detection of the asystole condition, attention is directed to Heinrich who teaches detecting an asystole condition and the asystole prevention therapy is delivered upon detection of the asystole condition (paras. [0064, 0066, 0067]). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Bardy to further include detecting an asystole condition and delivery of the asystole prevention therapy upon detection of the asystole condition as taught by Heinrich in order to provide a multifunctional implantable anti-arrhythmia device that provides therapy for all possible arrhythmias (bradycardia, tachycardia, asystole, etc.) that may be encountered in a patient.

Regarding claim 37, Bardy shows a method including sensing cardiac activity from a subcutaneous, non-intrathoracic location detecting a cardiac condition necessitating treatment in

response to the sensed cardiac activity, and delivering *one of* a plurality of cardiac therapies to treat the detected cardiac condition, the plurality of cardiac therapies comprising at least a tachycardia therapy, a bradycardia therapy, and an asystole prevention therapy (Paragraphs [0035], [0036], [0039]; Figs. 4-6, 9, 11, 15). Although Bardy fails to specifically teach detecting an asystole condition and the asystole prevention therapy is delivered upon detection of the asystole condition, attention is directed to Heinrich who teaches detecting an asystole condition and the asystole prevention therapy is delivered upon detection of the asystole condition (paras. [0064, 0066, 0067]). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Bardy to further include detecting an asystole condition and delivery of the asystole prevention therapy upon detection of the asystole condition as taught by Heinrich in order to provide a multifunctional implantable anti-arrhythmia device that provides therapy for all possible arrhythmias (bradycardia, tachycardia, asystole, etc.) that may be encountered in a patient.

The examiner has treated the "means for" limitations of claim 50 as invoking 35 U.S.C. 112, 6th paragraph. One with ordinary skill in the art will understand that the structure of the sensing circuitry (204) and subcutaneous electrodes (214) will perform the recited function of "sensing cardiac activity from a subcutaneous non-intrathroacic location", and the diagnostics circuitry (210) will perform the recited function of "detecting a cardiac condition in response to the sensed cardiac activity" and the shock therapy circuitry (216) and pacing therapy circuitry (230) will perform the function of "delivering one of a plurality of cardiac therapies". Although Bardy fails to specifically teach detecting an asystole condition and the asystole prevention therapy is delivered upon detection of the asystole condition, attention is directed to Heinrich

who teaches detecting an asystole condition and the asystole prevention therapy is delivered upon detection of the asystole condition (paras. [0064, 0066, 0067]). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Bardy to further include detecting an asystole condition and delivery of the asystole prevention therapy upon detection of the asystole condition as taught by Heinrich in order to provide a multifunctional implantable anti-arrhythmia device that provides therapy for all possible arrhythmias (bradycardia, tachycardia, asystole, etc.) that may be encountered in a patient.

The examiner considers that Bardy shows equivalent structure to the means for sensing cardiac activity from a subcutaneous, non-intrathoracic location, the means for detecting a cardiac condition necessitating treatment in response to the sensed cardiac activity, and the means for delivering *one of* a plurality of cardiac therapies to treat the detected cardiac condition, the plurality of cardiac therapies comprising at least a tachycardia therapy, a bradycardia therapy, and an asystole prevention therapy (Paragraphs [0035], [0036], [0039]; Figs. 4-6, 9, 11, 15).). Regarding claims 2-5, 22-25, 38-41 and 51-54, Bardy shows the plurality of cardiac therapies comprises a bradycardia pacing, cardiac resynchronization cardioversion/defibrillation) antitachycardia pacing, and defibrillation (Paragraphs [0035], [0036]).

With respect to claims 8 and 28, Bardy shows the one or more electrodes are configured for cardiac pacing (15, 27, 27', 1417, 1219) and sensing (23, 25, 26, 28, 1425, 1427) (Figs. 1-3, 10, 12-14, 18).

Regarding claim 13, Bardy shows a housing where the circuitry is situated and the housing is configured for implantation (Figs. 1-3, 10, 12-14, 18).

With respect to claims 14 and 29, Bardy shows the one or more electrodes include at least one electrode (15, 26, 28, 1417, 1219, 1425, 1427) disposed on the housing (Figs. 1-3, 10, 12-14, 18).

Regarding claims 15-18 and 30-32, Bardy shows delivering therapy of pacing pulses at a rate varying between 2 and 40 pulses per minute (20-120 stimuli per minute, where in the lower end of the range near 20 stimuli per minute, consciousness would not be restored) (Paragraph [0078])

Regarding claims 19 and 33, Bardy shows a housing within which the detection circuitry, energy delivery circuitry, and controller are situated, the housing is configured for implantation in a patient and the one or more electrodes (15, 26, 28, 1417, 1219, 1425, 1427) are disposed in or on the housing (Figs. 1-3, 10, 12-14, 18).

With respect to claims 20 and 34, Bardy shows the housing is configured to have an arcuate shape (Figs. 12-14, 18).

Regarding claims 35-36, Bardy shows the one or more electrodes (23, 25, 26, 27, 27', 28) comprise at least one subcutaneous, non-intrathoracic electrode array coupled to the housing via a lead (21) (Figs 1-6, 9-13)

With respect to claims 44, 48, 57 and 60, Bardy shows detecting the cardiac condition at a subcutaneous, non-intrathoracic location (via electrodes 23, 25, 26, 28, 1425, 1427) and energy for the plurality of cardiac therapies is provided from a subcutaneous, non-intrathoracic source (within the housing) (Figs. 1-3, 10, 12-14, 18).

Regarding claims 48-49 and 61-62, Bardy shows delivering monophasic waveforms and delivering multiphasic waveforms (Paragraphs [0035], [0060], [0072]).

The examiner has treated the "means for" limitations of claims 57 and 60-62 as invoking 35 U.S.C. 112, 6th paragraph. One with ordinary skill in the art will understand that the structure of the sensing circuitry (204) and subcutaneous electrodes (214) and diagnostics circuitry (210) will perform the recited function of "detecting the cardiac condition at a subcutaneous non-intrathroacic location", the structure of the power source (220) will perform the recited function of "supplying energy . . . from a subcutaneous non-intrathoracic source" and the shock therapy circuitry (216) and pacing therapy circuitry (230) will perform the function of "delivering monophasic waveforms" and "delivering multiphasic waveforms"

As explained above, the examiner considers that Bardy shows equivalent structure to the means for detecting the cardiac condition at a subcutaneous non-intrathroacic location, the means for supplying energy . . . from a subcutaneous non-intrathroacic source, the means for delivering monophasic waveforms and the means for delivering multiphasic waveforms. See rejections above for claims 57 and 60-62.

The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

5. Claims 6, 26, 42 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy et al. (2002/0035376) in view of Heinrich (2002/0082658) as applied to claims 1, 21, 37 and 50 above and further in view of Brockway et al. (4,562,841).

Bardy and Heinrich are as explained before. Although Bardy and Heinrich fail to show the cardiac therapy comprises a rate smoothing therapy, attention is directed to Brockway who teaches rate smoothing pacing therapy. Brockway teaches that a rate smoothing therapy operates to ensure that the pacing rate from pacing interval to pacing interval does not change by more

than a selected percentage of the previous interval thus providing a smoother less erratic pacing rhythm. (Col. 6, lines 49-54). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the system and method of Bardy and Heinrich to include a rate smoothing pacing therapy in order to ensure that the pacing rate from pacing interval to pacing interval does not change by more than a selected percentage of the previous interval thus providing a smoother less erratic pacing rhythm.

6. Claims 6, 26, 42 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy et al. (2002/0091414) in view of Heinrich (2002/0082658) as applied to claims 1, 21, 37 and 50 above and further in view of Brockway et al. (4,562,841).

Bardy and Heinrich are as explained before. Although Bardy and Heinrich fail to show the cardiac therapy comprises a rate smoothing therapy, attention is directed to Brockway who teaches rate smoothing pacing therapy. Brockway teaches that a rate smoothing therapy operates to ensure that the pacing rate from pacing interval to pacing interval does not change by more than a selected percentage of the previous interval thus providing a smoother less erratic pacing rhythm. (Col. 6, lines 49-54). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the system and method of Bardy and Heinrich to include a rate smoothing pacing therapy in order to ensure that the pacing rate from pacing interval to pacing interval does not change by more than a selected percentage of the previous interval thus providing a smoother less erratic pacing rhythm.

7. Claims 7, 27, 43 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy et al. (2002/0035376) in view of Heinrich (2002/0082658) as applied to claims 1, 21, 37 and 50 above and further in view of Kieval et al. (5,814,079).

Bardy and Heinrich are as explained before. Although Bardy and Heinrich fail to show the cardiac therapy comprises a sub-threshold stimulation therapy, attention is directed to Kieval who teaches a sub-threshold stimulation therapy. Kieval teaches that a sub-threshold stimulation therapy is used to prevent a tachyarrhythmia by effecting maximal cardiac relaxation and suppressing aberrant electrical activity (Abs) and sub-threshold stimulation therapy is used in combination with cardioversion/defibrillation therapy to reduce the cardioversion shock energy required (Col. 5, lines 31-47). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the system and method of Bardy and Heinrich to include a sub-threshold stimulation therapy in order to prevent a tachyarrhythmia by effecting maximal cardiac relaxation and suppressing aberrant electrical activity and also to reduce the cardioversion shock energy required.

8. Claims 7, 27, 43 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy et al. (2002/0091414) in view of Heinrich (2002/0082658) as applied to claims 1, 21, 37 and 50 above and further in view of Kieval et al. (5,814,079).

Bardy and Heinrich are as explained before. Although Bardy and Heinrich fail to show the cardiac therapy comprises a sub-threshold stimulation therapy, attention is directed to Kieval who teaches a sub-threshold stimulation therapy. Kieval teaches that a sub-threshold stimulation therapy is used to prevent a tachyarrhythmia by effecting maximal cardiac relaxation and suppressing aberrant electrical activity (Abs) and sub-threshold stimulation therapy is used in combination with cardioversion/defibrillation therapy to reduce the cardioversion shock energy required (Col. 5, lines 31-47). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the system and method of Bardy and

Heinrich to include a sub-threshold stimulation therapy in order to prevent a tachyarrhythmia by effecting maximal cardiac relaxation and suppressing aberrant electrical activity and also to reduce the cardioversion shock energy required.

9. Claims 17-18 and 31-32 are rejected under 35 U.S.C. 103(a) as being obvious over Bardy et al. (2002/0035376) in view of Heinrich (2002/0082658) as applied to claims 1, and 21 above. Bardy and Heinrich are as explained before. Bardy and Heinrich disclosed the claimed invention except for the asystole prevention therapy comprises delivery of pacing pulses at a rate lower than a pacing rate associated with the bradycardia therapy and it is a fixed or variable rate. It would have been an obvious design choice to one with ordinary skill in the art at the time of the invention to provide an asystole prevention therapy comprising delivery of pacing pulses at a fixed or variable rate lower than a pacing rate associated with the bradycardia therapy, since applicant has not disclosed that this lower rate provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any pacing rate such as the pacing rated taught by Bardy and Heinrich for treating asystole and bradycardia.

Response to Arguments

10. Applicant's arguments with respect to claims 1-8, 13-44, 47-57 and 60-62 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Droesch Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kristen Droesd Mullen

kdm

KRISTEN D. MULLEN
PRIMARY EXAMINER
TECHNOLOGY CENTER 3700